K013361

FEB 2 6 2002

510(k) SUMMARY

Submitter's name: Duracare Medical Equipment, L.C.
6182 Idlewild St., Fort Myers, FL 33912
(941) 791-4000

Date summary prepared: October 5, 2001

Device name:

Proprietary name:	WIN-2™ Tango Elite NP
Common or usual name:	Power chair
Classification name:	Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

WIN-1 Tango submitted by Duracare Medical Equipment, L.C. and cleared for marketing under 510(k) #K000204.

Description of the device:

The WIN-2 Tango Elite NP is a powered wheelchair for use both indoors and outdoors. It is battery powered, has two 0.25 horsepower motors, and a controller unit with joystick. It is designed for a single rider who controls the speed and direction of the chair's movement with the joystick. It can be disassembled for transport, and a battery charger is supplied as an accessory. The only difference between the WIN-1 and the WIN-2 wheelchairs is the controller.

Intended use of device:

The intended use of the WIN-2 Tango Elite NP is to provide mobility for a person restricted to a sitting position.

Technological characteristics:

The device features of the WIN-1 and the WIN-2 are identical except for the difference in controllers. The use parameters vary only in minor ways such as maximum speeds.

Testing conducted:

Results were reported from testing of relevant portions of the *ANSI/RESNA Wheelchairs Vol. 2 Standard.*. Additional tests were conducted on electromagnetic compatibility, functional testing reported on the Summary Matrix, the upholstery material, and the battery charger.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

SECTION 3 - INTENDED USE

Intended use of device:

The intended use of the WIN-2 Tango Elite is to provide mobility for a person restricted to a sitting position. This is consistent with the intended use of other powered wheelchairs.

Intended use of predicate device:

The intended use of the WIN-1 Tango is to provide mobility for a person restricted to a sitting position.

Comparison:

These two models have the identical intended use statements.

Labeling:

The intended use of the WIN-2 is implied in the User Manual by the use of phrases such as "allowing you the freedom to go places you have always wanted to go" and "designed for maximum maneuverability even in narrow and tight spaces." A draft copy of the Users Manual can be found in Appendix II.

A copy of the Users Manual for the WIN-1 model can be found in Appendix VI. The intended use sheet from K#000204 is provided in Appendix IV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Durable Medical Equipment, Inc.
c/o Mr. Robert S. McQuate
R. S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, AZ 85032

Re: K013361
Trade/Device Name: WIN-2™ Tango Elite NP
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: February 4, 2002
Received: February 5, 2002

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

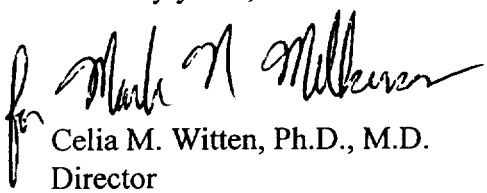
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K013361

Device name: WIN-2™ Tango Elite NP

Indications for Use:

To provide mobility for a person restricted to a sitting position.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013361

Prescription Use _____ OR Over-The-Counter Use ✓